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| 10/590,369 | 05/17/2007 | Thomas M. Soukup | H583.106.102 | 8389 |
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| DICKE, BILLIG & CZAJA FIFTH STREET TOWERS 100 SOUTH FIFTH STREET, SUITE 2250 MINNEAPOLIS, MN 55402 | | | EXAMINER PORTER, JR, GARY A | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---------------------------------------|--|--|
| Office Action Summary | Application No. 10/590,369 | Applicant(s) SOUKUP, THOMAS M. | |
| | Examiner GARY A. PORTER, JR | Art Unit 3766 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 22-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/23/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-21 in the reply filed on May 7, 2009 is acknowledged.
2. Claims 22-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 7, 2009.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-3, 5, 9, 13, 15, 17, 18, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Werner et al. (U.S. Patent 6,038,481).
5. Regarding Claim 1, Werner teaches an adaptor assembly comprising a housing comprising a first side 262 and a second side 262' wherein the sides are moveably relative to one another. Werner further teaches that the adaptor defines a cavity 270 when sides 262 and 262' are in a closed configuration. Lastly, Werner teaches that the

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cavity 270 is of sufficient size to receive an implantable lead (col. 11, lines 4-22; Fig. 14-18).

6. In regards to Claim 2, Werner teaches electrical contacts 272 and 274 supported by the first side of the housing 262 (col. 11, lines 19-22).

7. With regards to Claim 3, Werner teaches that contacts 272 and 274 are axially spaced relative to one another (Fig. 15, 180).

8. Regarding Claim 5, Werner teaches the first side of the housing 262 defines a first channel, i.e. a first semi-circular tubular section (Fig. 14).

9. In regards to Claim 9, Werner teaches the second side of the housing 262' defines a second channel, i.e. a second semi-circular tubular section (Fig. 14).

10. With regards to Claim 13, Werner teaches contacts 272 and 274 further define a hinge which connects halves 262 and 262' (col. 11, lines 37-40).

11. Regarding Claim 15, Werner teaches a tab 292 or 294 extending from the housing (Fig. 17).

12. In regards to Claim 17, Werner teaches an implantable lead 12 disposed in the cavity 270 (col. 11, lines 54-61).

13. With regards to Claim 18, Werner teaches a stylet 32 extending through the housing and into a lumen 38 defined by the implantable lead (col. 11, lines 54-61).

14. Regarding Claim 19, Werner teaches that an electronic device is electrically connected to the lead (col. 7, lines 6-26), although not shown in the specific embodiment relied upon for convenience of the illustration (col. 10, line 64-col. 11, line 4).

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15. In regards to Claim 20, Werner teaches that the electronic device is a temporary pacemaker (col. 7, lines 6-26).

16. Claims 1, 2 and 5-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Hansen et al. (US Pub. 2005/0177199).

17. Regarding Claim 1, Hansen teaches a housing 70 comprising a first side 72 and a second side 74 that move relative to each other between a closed configuration and an open configuration. Hansen further teaches that when in a closed configuration, sides 72 and 74 form a cavity 42. Lastly, Hansen teaches that the terminal end 126 of a lead is placed within recesses 82 before closing the halves to form cavity 42 (Fig. 15; Section [0052]).

18. In regards to Claim 2, Hansen teaches a plurality of electrical contacts 79 and 81 supported by the first side of the housing (Section [0053-0054]).

19. With regards to Claims 5 and 6, Hansen teaches first portion 72 has a channel 82 with a guiding portion and a tapered portion (Fig. 13).

20. Regarding Claim 7, Hansen teaches that the guiding portion, i.e. the tubular section of constant diameter, is co-axially aligned with a lumen defined by an implantable lead (Fig. 13).

21. In regards to Claim 8, Hansen teaches that a lead is inserted into the first channel 82 (Fig. 13). The Examiner notes that in the art of lead implantation, it is known that stylets can be inserted through a lumen of an implantable lead in order to allow steering of the lead, as evidenced by Honeck (U.S. Pub 2005/0090884). As such, since

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the stylet fits within the lead, the channel of Hansen is inherently of the right dimension to house a lead and stylet since the lead defines the maximum diameter of a lead and stylet combination. In other words, since the stylet fits within the lead it does not change the diameter of the lead itself.

22. In regards to Claims 9 and 10, Hansen teaches second portion 74 has a channel 82 with a guiding portion and a tapered portion (Fig. 13).

23. Regarding Claim 11, Hansen teaches that the guiding portion, i.e. the tubular section of constant diameter, is co-axially aligned with a lumen defined by an implantable lead (Fig. 13).

24. In regards to Claim 12, Hansen teaches that a lead is inserted into the second channel 82 (Fig. 13). The Examiner notes that in the art of lead implantation, it is known that stylets can be inserted through a lumen of an implantable lead in order to allow steering of the lead, as evidenced by Honeck (U.S. Pub 2005/0090884). As such, since the stylet fits within the lead, the channel of Hansen is inherently of the right dimension to house a lead and stylet since the lead defines the maximum diameter of a lead and stylet combination. In other words, since the stylet fits within the lead it does not change the diameter of the lead itself.

25. In regards to Claim 13, Hansen teaches a hinge 76 connecting the first side of the housing to the second side of the housing (Section [0052]).

26. Claims 1, 2 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Boling (U.S. Pub. 2003/0195602).

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27. Regarding Claim 1, Boling teaches a housing comprising a first side 3007 and a second side 3001 that are movable relative to one another between an open and closed configuration. Boling also teaches that when in a closed configuration, the first side and second side form a cavity that is dimensioned to receive an implantable lead (Section [0263]; Fig. 45 and 51).

28. In regards to Claims 2 and 4, Boling teaches a plurality of electrical spring contacts supported by the first side 3007 of the housing (Section [0274]; Fig. 43).

Claim Rejections - 35 USC § 103

29. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

30. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen et al. (US Pub. 2005/0177199). Hansen discloses hinge connecting the two halves of the adapter. Hansen further discloses that the hinge is a living hinge but other types and styles of hinges may be used (Section [0052]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a hinge made of a web of polymeric material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

31. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Werner et al. (U.S. Patent 6,038,481) in view of McCready et al. (U.S. Patent 4,254,763).

Werner discloses all of the claimed invention except for a sheet held against the tab by a clamp. However, McCready teaches, as is known in the surgical arts, that surgical drapes are used in tandem with clamps in order to secure instruments during surgical procedures (Abstract; Fig. 1). One of ordinary skill in the art would have recognized the need to stabilize the adapter of Werner during implantation of the cardiac device in order to insure the adapter does not fall on the floor or other unsanitary area during surgery. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device in the Werner reference to include a surgical drape and clamp, as taught and suggested by McCready, for the purpose of securing the adapter during surgery.

32. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Werner et al. (U.S. Patent 6,038,481). Werner discloses that the electronic device is a temporary pacemaker (col. 7, lines 6-26) but does not disclose that the device is or can be a defibrillator analyzer. However, Werner does disclose that certain implantable devices have pacing, cardioverting and defibrillating capabilities. Werner also discloses that the adapter is capable of use with such systems in order to test that the entire device is working properly. This would include defibrillating capabilities. One of ordinary skill in the art would have recognized the benefits of connecting the device to a

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defibrillation analyzer in order to ensure the proper functioning of the defibrillator.

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device in the Werner reference to include a connection to a defibrillation analyzer, as taught and suggested by Werner, for the purpose of ensuring the proper functioning of the defibrillator.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GARY A. PORTER, JR whose telephone number is (571)270-5419. The examiner can normally be reached on Monday - Thursday, 8AM - 5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571)272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G. A. P./
Examiner, Art Unit 3766

/Carl H. Layno/
Supervisory Patent Examiner, Art
Unit 3766